DEC - 4 2000

510(k) Summary

K 002987

1.0 Date Prepared

September 22, 2000

2.0 Submitter (Contact)

Martin D. Sargent
Regulatory Affairs Manager
Medtronic Xomed
Jacksonville, FL
(904) 279-7586

3.0 Device Name

Proprietary Name:	Medtronic Xomed Monopolar Energized Blade (The tradename has not been finalized at this time)
Common Name(s):	Microresection coagulator
Classification Name(s):	Ear, nose, and throat bur; electrosurgical cutting and coagulation device and accessories

4.0 Device Classification

Classification Name: Ear, nose, and throat bur; electrosurgical cutting and coagulation device and accessories

Procode 77EQJ	Class I	21 CFR § 874.4140
Procode 79GEI	Class II	21 CFR § 878.4400

5.0 Device Description

The Monopolar Energized Blade provides mechanical microresection with internal irrigation, suction, and electrocautery coagulation in one device.

6.0 Indications for Use

The Monopolar Energized blade is intended for use by qualified surgeons familiar with radio-frequency electrosurgery techniques.

The device is indicated for the incision and removal of soft and hard tissue or bone in general otorhinolaryngology, head and neck procedures, and to control bleeding.

Nasopharyngeal/laryngeal indications include adenoidectomy, tracheal procedures, laryngeal polypectomy, laryngeal lesion debulking, and tonsillectomy.

7.0 Substantial Equivalence

The design, technology, features, function, and intended use of the mechanical tissue microresection feature of the Monopolar Energized Blade is substantially equivalent to Medtronic Xomed ENT microresection blades originally described in K954912.

The design, technology, function, and intended use of the electrosurgical coagulation feature is substantially equivalent to commonly available preamendment suction coagulators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2001

Mr. Martin D. Sargent
Regulatory Affairs Manager
Medtronic Xomed
6743 Southpoint Drive N
Jacksonville, Florida 32216-0980

Re: K002987
Trade Name: Medtronic Xomed Monopolar Energized Blade
Regulatory Class: II
Product Code: GEI
Dated: September 22, 2000
Received: September 25, 2000

Dear Mr. Sargent:

This letter corrects our substantially equivalent letter of December 4, 2000, regarding the Product Code.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Susan Walker, MD

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K002987

Device Name: Monopolar Energized Blade

Indications for Use:

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(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhauser

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K002987

Prescription Use ✓ Or Over-the-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)